

# Emerging Tobacco Products

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*The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention*

Centers for Disease Control and Prevention  
Office on Smoking and Health



## Context: Burned Tobacco is Still a Problem



**“The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.”**

The health consequences of smoking – 50 years of progress: a report of the Surgeon General. – Atlanta, GA. : U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

# Overview

- 1 What are emerging tobacco products?
- 2 Who is using emerging products?
- 3 What are health risks of emerging products?
- 4 Which policy approaches are appropriate for emerging products?

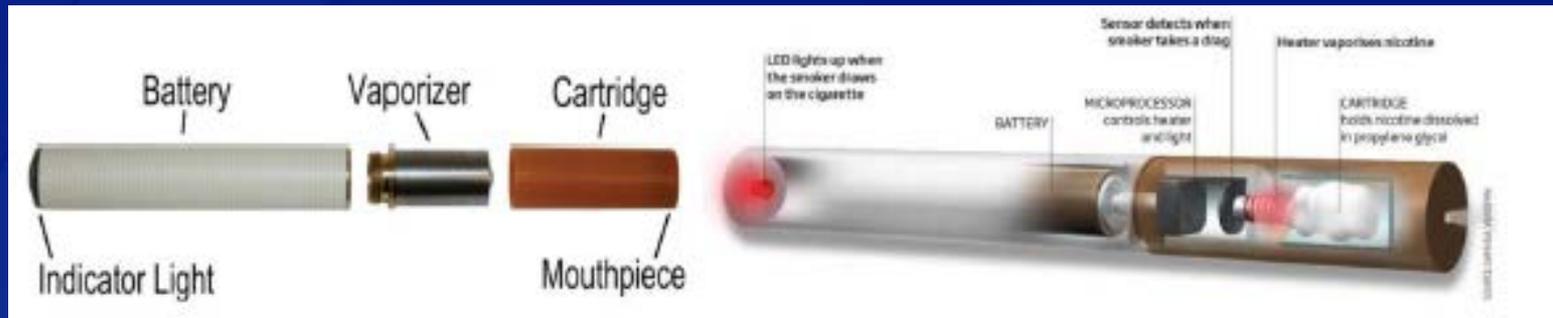
# What Are ENDS?

## Electronic Cigarettes and Vaping Devices

Product	Description	Some Brands
<b>Disposable e-cigarette</b> 	Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah.	NJOY OneJoy, Aer Disposable, Flavorvapes
<b>Rechargeable e-cigarette</b> 	Cigarette-shaped device consisting of a battery that connects to an atomizer used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and /or how many puffs may be taken consecutively.	Blu, GreenSmoke, EonSmoke
<b>Pen-style, medium-sized rechargeable e-cigarette</b> 	Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing to regulate length and frequency of puffs.	Vapor King Storm, Totally Wicked Tornado
<b>Tank-style, large-sized rechargeable e-cigarette</b> 	Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customizing battery capacity. Can be easily modified.	Volcano Lavatube

# ENDS

- ❑ Delivers nicotine-containing aerosol by heating a solution (typically propylene glycol or glycerol/ glycerin nicotine, and flavoring agents, and other additives)
- ❑ Long-term health effects of inhaled propylene glycol and glycerin are unknown



Hutzler, Paschke, Kruschinski, et al. Chemical hazards present in liquids and vapors of electronic cigarettes. Arch Toxicol 2014

# ENDS Aerosol is not *“Harmless Water Vapor”*

- ❑ Nicotine: 0-36 mg/ml
- ❑ Flavorings/additives often not disclosed
- ❑ Some analyses show presence of potentially allergenic compounds such as cinnamic aldehyde (highly toxic to human embryonic stem cells)
- ❑ Overheating could lead to production of carcinogens, such as formaldehyde, acetaldehyde, acrolein

Bhatnagar et al. Electronic cigarettes: a policy statement from the American Heart Association. *Circulation*. 2014;130:1418-36.

Behar, Davis, Wang, et al. Identification of toxicants in cinnamon flavored electronic cigarette refill fluids. *Toxicology in vitro* 2014.

Hutzler, Paschke, Kruschinski, et al. Chemical hazards present in liquids and vapors of electronic cigarettes. *Arch Toxicol* 2014



## ENDS Other Purposes

- Some ENDS can be used to deliver other substances, like marijuana and caffeine



**Lehigh Vapor**  
484-429-6978

[Blog](#) [About Us](#)  
[Home](#) [Liquid](#) [A](#)

### Caffeitine

A line of eLiquid that added pure extract caffeine to the traditional nicotine based liquid blend version and that of a pure caffeine, no nicotine version for customers to choose from. Caffeitine US trademark registration pending.

**WARNINGS:**



# ENDS As Cessation Devices

# Not Approved as a Cessation Device Center for Drug Evaluation and Research

- ❑ In 8 years companies have not approached FDA for approval



Original Article

## Electronic Cigarette Use Among Patients With Cancer

Characteristics of Electronic Cigarette Users and Their Smoking Cessation Outcomes

Sarah P. Borderud, MPH<sup>1</sup>; Yuelin Li, PhD<sup>2</sup>; Jack E. Burkhalter, PhD<sup>1</sup>; Christine E. Sheffer, PhD<sup>2</sup>; and Jamie S. Ostroff, PhD<sup>1\*</sup>

**BACKGROUND:** Given that continued smoking after a cancer diagnosis increases the risk of adverse health outcomes, patients with cancer are strongly advised to quit. Despite a current lack of evidence regarding their safety and effectiveness as a cessation tool, electronic cigarettes (E-cigarettes) are becoming increasingly popular. To guide oncologists' communication with their patients about E-cigarette use, this article provides what to the authors' knowledge is the first published clinical data regarding E-cigarette use and cessation outcomes among patients with cancer. **METHODS:** A total of 1074 participants included smokers (patients with cancer) who recently enrolled in a tobacco treatment program at a comprehensive cancer center. Standard demographic, tobacco use history, and follow-up cessation outcomes were assessed. **RESULTS:** A 3-fold increase in E-cigarette use was observed from 2012 to 2013 (10.6% vs 38.5%). E-cigarette users were more nicotine dependent than nonusers, had more prior quit attempts, and were more likely to be diagnosed with thoracic and head or neck cancers. Using a complete case analysis, E-cigarette users were as likely to be smoking at the time of follow-up as nonusers (odds ratio, 1.0; 95% confidence interval, 0.5-1.7). Using an intention-to-treat analysis, E-cigarette users were twice as likely to be smoking at the time of follow-up as nonusers (odds ratio, 2.0; 95% confidence interval, 1.2-3.3). **CONCLUSIONS:** The high rate of E-cigarette use observed is consistent with recent articles highlighting increased E-cigarette use in the general population. The current longitudinal findings raise doubts concerning the usefulness of E-cigarettes for facilitating smoking cessation among patients with cancer. Further research is needed to evaluate the safety and efficacy of E-cigarettes as a cessation treatment for patients with cancer. *Cancer* 2014;000:000-000. © 2014 American Cancer Society.

Borderud, S. P., Li, Y., Burkhalter, J. E., Sheffer, C. E. and Ostroff, J. S. (2014), Electronic cigarette use among patients with cancer: Characteristics of electronic cigarette users and their smoking cessation outcomes. *Cancer*. doi: 10.1002/cncr.28811

# ENDS and Cessation

**Table 2. Population Studies of the Association Between E-Cigarette Use and Cessation of Conventional Cigarette Smoking**

Study	Location and Study Design	Odds of Quitting (95% CI)
Longitudinal studies		
Adkison et al <sup>4</sup> (2013)	US, UK, Canada, Australia (ITC), surveyed, 1 y apart	0.81 (0.43–1.53)*
Vickerman et al <sup>80</sup> (2013)	US quit-line callers from 6 states surveyed at enrollment and 7 mo later	0.50 (0.40–0.63)†
Grana et al <sup>79</sup> (2014)	US sample drawn from a nationally representative Internet panel, 1 y apart	0.76 (0.36–1.60)
Choi and Forster <sup>81</sup> (2014)	Midwestern young adults, 1 y apart	0.93 (0.19–4.63)
Cross-sectional study		
Popova and Ling <sup>82</sup> (2013)	US sample drawn from a nationally represented Internet panel	0.69 (0.52–0.94) *
All studies		
Pooled‡		0.61 (0.50–0.75)

CI indicates confidence interval; E-cigarette, electronic cigarette; and ITC, International Tobacco Control.

\*Odds ratios obtained by contacting authors.

†Computed by authors of this report on the basis of the numbers reported.

‡Estimated with a random-effects meta-analysis using Stata 12.1 metan. There was no evidence of heterogeneity ( $P=0.28$ ) or evidence of publication bias with the use of a funnel plot.

Grana, Benowitz, Glantz. E-cigarettes: a scientific review. *Circulation* 2014;129:1972-86.

# Cessation: Randomized Trials

- 2 trials conducted with control arms
  - Caponnetto et al., 2013 (3 e-cigarette arms)
    - Participants not interested in quitting
    - All arms reduced cigs/day, no difference in quits
  - Bullen et al., 2013
    - Participants wanted to quit
    - Nicotine e-cigarette, zero nicotine e-cigarette, NRT patch
    - 6 month follow-up
    - 50% reduction cigs/day (57%, 45%, 41%,  $p=0.08$ )
    - Quitting 7.3%, 4.1%, 5.8% ( $p=0.5$ )

# Cessation in cancer patients

## Borderud et al, 2014

- Patients presenting to Memorial Sloan Kettering Cancer Center 2012-2013 screened for tobacco use, users referred to Tobacco Cessation Program (n=4504)
- Those willing to enroll in treatment program included in study (n=1074)
  - Assessed for e-cigarette use
  - Follow up at 6-12 months for cessation status (n=414)
- Findings:
  - 26% reported past 30 day use of e-cigarettes at baseline; 92% of e-cigarette users were also smoking.
  - Quarterly prevalence increased from 10.6% to 38.5%

# Cessation in cancer patients

## Continued

### ❑ E-cigarette users :

- Smoked more cigarettes/day
- Reported higher nicotine dependence scores
- Had more frequent and longer duration of prior quit attempts
- No difference in quitting motivation or confidence

### ❑ At follow up:

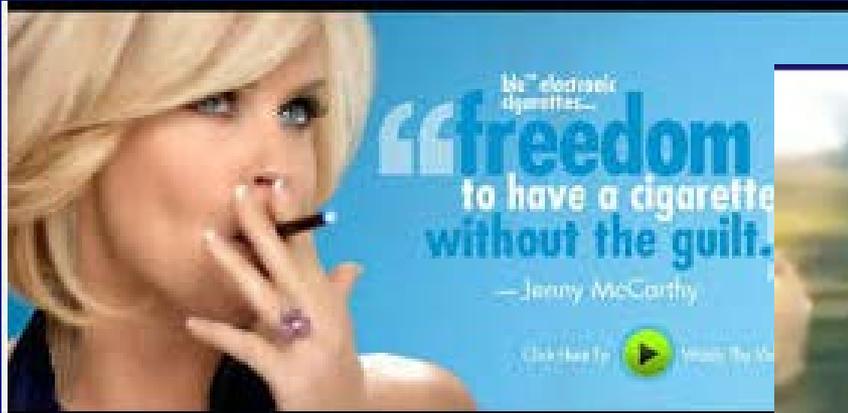
- 7-day point prevalence of smoking abstinence was no different in e-cigarette users and non-users (44.4% vs. 43.1%).
- E-cigarette users were less likely to have been abstinent for > 24 hrs
- After adjustment, e-cigarette users as likely to be smoking at follow up as non-users.

# Marketing

# ENDS Advertising Expenditures across media markets

- ❑ 2011: \$6.4 million
- ❑ 2012: \$18.3 million
- ❑ 2013: >\$80 million

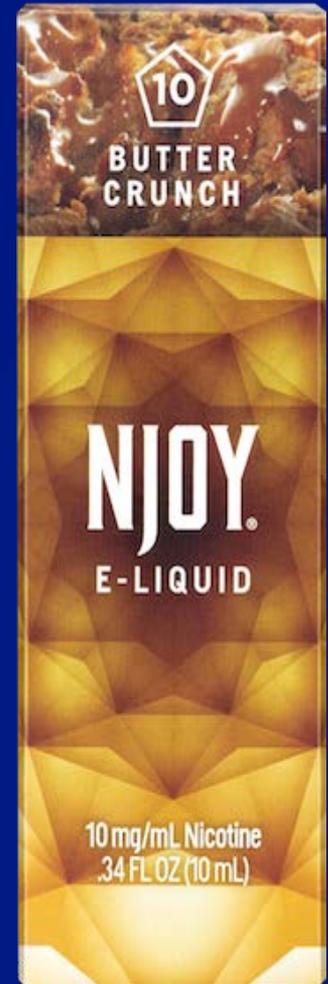
# Celebrity spokespeople



# Glamorous women



# Hundreds of flavors



# Sports and music events sponsorship



**blu ELECTRONIC CIGARETTES PRESENTS**

*electric lounge*

MARCH 14-16, 2013 • 418 E. 6th St. • AUSTIN, TX

thursday	friday	saturday
<b>DAY 12:00 - 1:00</b> <b>DMX FIRE</b> DAVEY B. COLVILLE PHIL BISHOPMAN THE BROTHERS BILLY BOWEN BOBBI BOWEN	<b>DAY 12:00 - 1:00</b> <b>FUTURE CLASSIC / BOND SERVICE</b> KYLEE JAC CHAMBER BETH BUBBY HYPERCY DRAGONFLY	<b>DAY 12:00 - 1:00</b> <b>ON RECORDS / LAVISH HABITS</b> BILLY BOWEN PHIL BISHOPMAN THE BROTHERS BILLY BOWEN BOBBI BOWEN CHAMBER BETH BUBBY HYPERCY
<b>NIGHT 11:00 - 1:00</b> <b>FIREPOWER</b> DAVEY B. COLVILLE PHIL BISHOPMAN THE BROTHERS BILLY BOWEN BOBBI BOWEN	<b>NIGHT 11:00 - 1:00</b> <b>ATTACH &amp; COMPARE</b> PHIL BISHOPMAN THE BROTHERS BILLY BOWEN BOBBI BOWEN	<b>NIGHT 11:00 - 1:00</b> <b>BLU'S BEST CLUB TO GET</b> DAVEY B. COLVILLE PHIL BISHOPMAN THE BROTHERS BILLY BOWEN BOBBI BOWEN

Photo credit: Justin P. [unreadable] / [unreadable] Photo credit: Justin P. [unreadable] / [unreadable]

BLU ELECTRONIC CIGARETTES PRESENTS

## Use in smoke-free areas



**Smoke** Anywhere  
Smoke when and where you want.

Dj HeavyGrinder  
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# Cheaper price

Smoking Everywhere E-Cigarette is cheaper than smoking real ci



**CHEAPER**

Smoking Everywhere  
chemicals like tradition  
like a real cigarette, fe  
cigarette... It also may



each e-cig is  
**= ABOUT 3 PACKS  
OF CIGARETTES**

**1.8%  
MENTHOL**



Side courtesy Pam Ling, UCSF

## Social networking

Blu e-Cigs finally launches new 'Smart Pack' for social smoking, tweakable nicotine intake



THE LATEST SUPERSMOKER

# BLUETOOTH

World first! In 2007, we introduced the first electronic cigarette in the world; 7 years later, we are changing the world of electronic smoking for good with the first Supersmoker that can be used to make calls and receive via Bluetooth and play music via the built-in microphone!



# Placement Next to Candy



<http://www.countertobacco.org/news/2014/09/12/njoy-brags-about-e-cigarette-placement-among-candy>



# Health Claims

New research on the dangers of smoking to young women and their unborn babies can send chills down any woman's spine. We now have several more compelling reasons to help women realize how important it is to quit smoking or switch to e-cigarettes - ideally **e-cigarettes with no nicotine**.



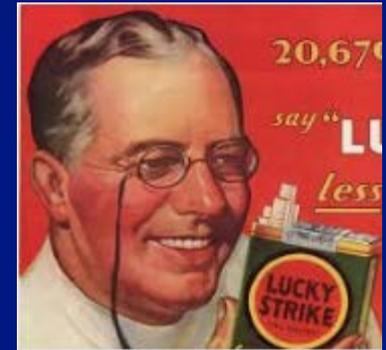
Quitting smoking at any point during pregnancy reduces the chance of complications. Of course, the sooner, the better!

Side courtesy Pam Ling, UCSF



A screenshot of the NutriCigs website. The top navigation bar includes 'Home', 'Shop', 'How It Works', 'Why Us', 'Testimonials', 'FAQ', and 'Blog'. Below the navigation is a banner for 'SAY GOOD-BYE TO SLEEPLESS NIGHTS' featuring a smiling woman and a NutriCigs e-cigarette. The bottom section displays three product categories: 'SLIM NutriCigs ALL-NATURAL APPETITE SUPPRESSANT', 'ENERGY NutriCigs ALL-NATURAL ENERGY BOOSTER', and 'SLEEP NutriCigs ALL-NATURAL SLEEP AID'. A 'TRY NOW' button is visible in the banner.

# Physician Endorsement



# What tactics lead to youth smoking?

- Exposure to ads
- Themes in advertising that resonate with youth
- Low prices and price-reducing promotions
- Ease of access to a product
- Candy and fruit-flavored products
- Health claims
- Products that are easier to use

## Preventing Tobacco Use Among Youth and Young Adults

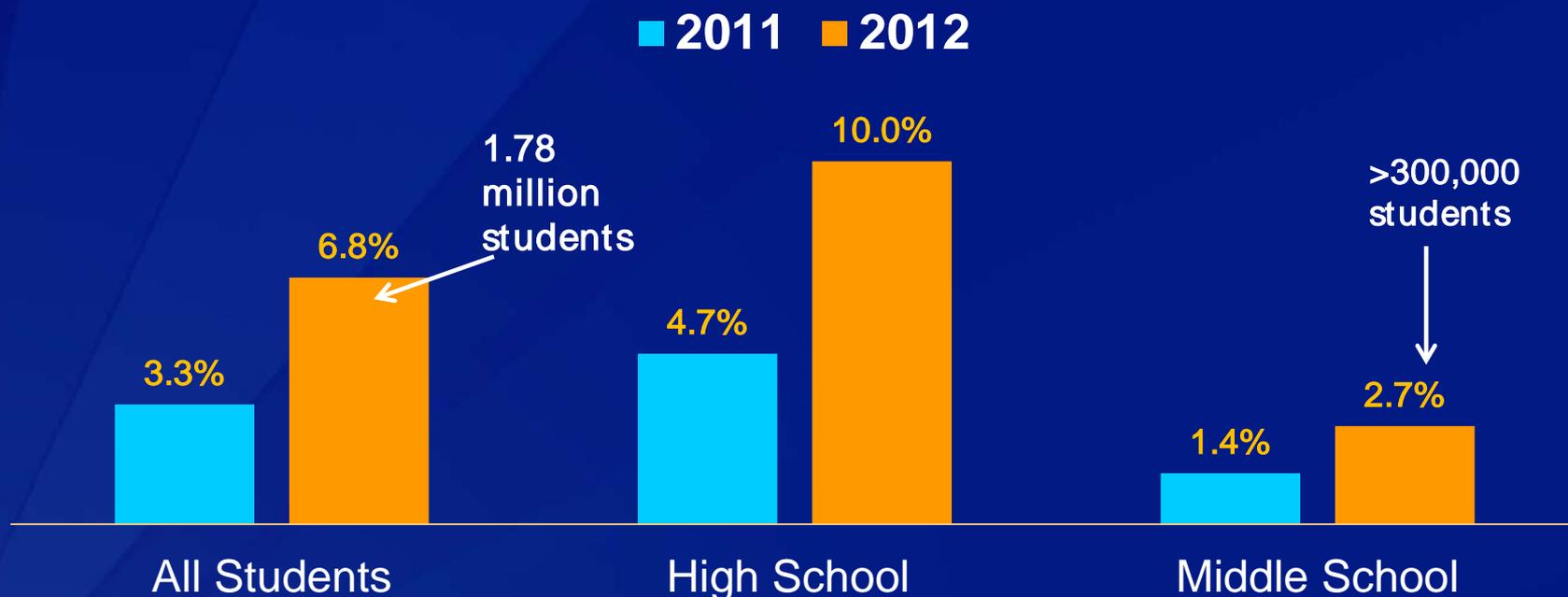
A Report of the Surgeon General



U.S. Department of Health and Human Services

# E-cigarette ever use more than doubled\* between 2011 and 2012 among students

*Youth E-cigarette Ever Use, National Youth Tobacco Survey, United States*



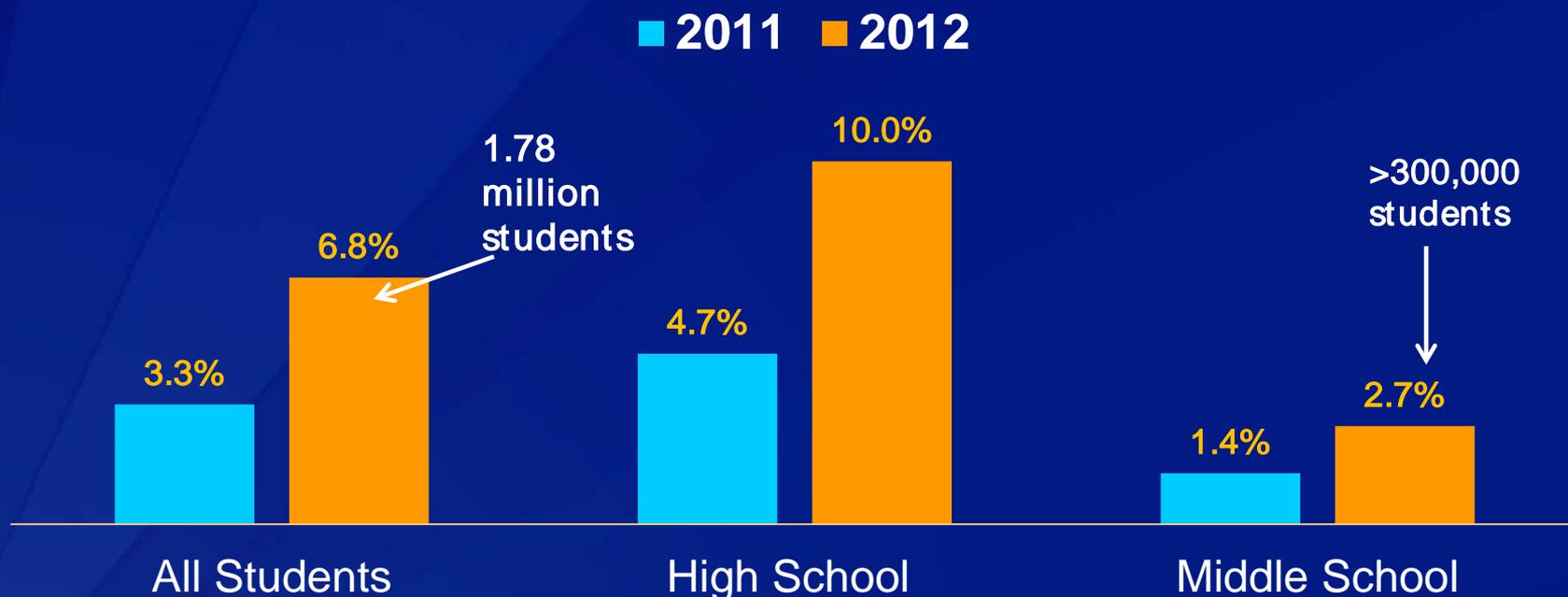
\*Statistically different ( $p < 0.05$ )

Centers for Disease Control and Prevention (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students— United States, 2011–2012." *Morbidity and Mortality Weekly Report* 62(35): 729-730.

# Trends in Use

# E-cigarette ever use more than doubled\* between 2011 and 2012 among students

*Youth E-cigarette Ever Use, National Youth Tobacco Survey, United States*

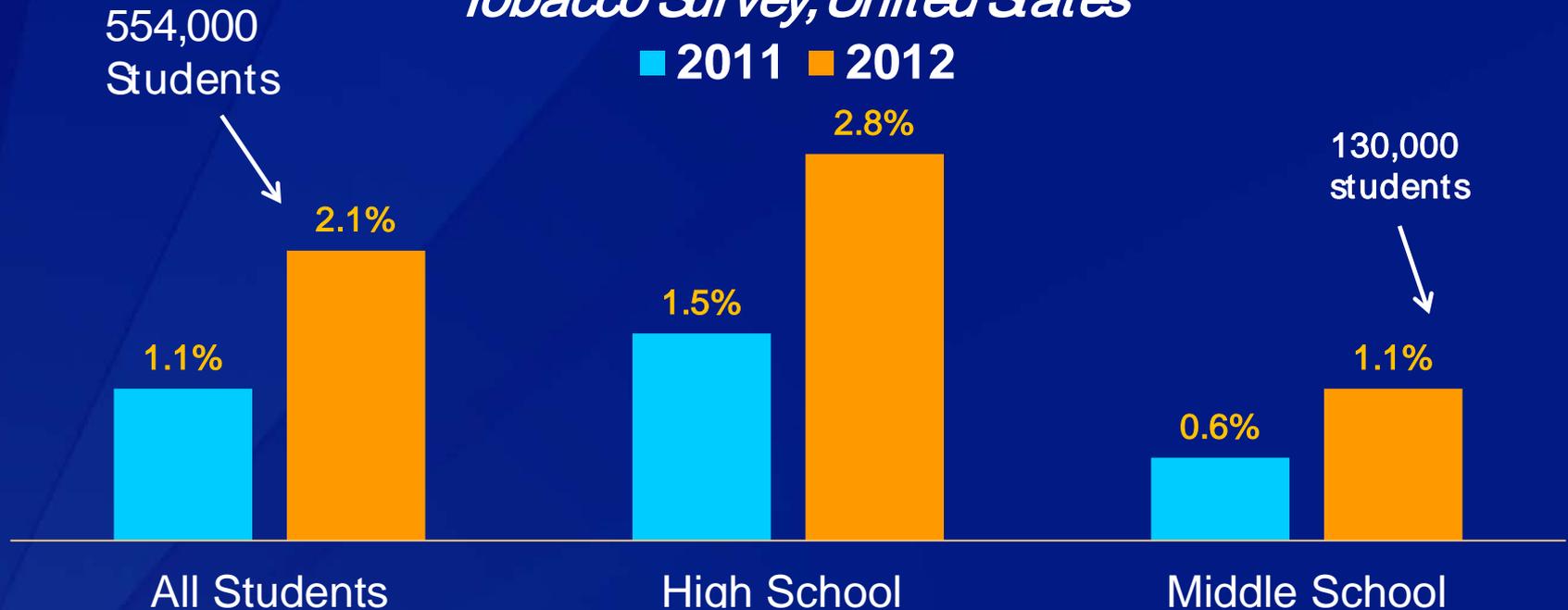


\*Statistically different ( $p < 0.05$ )

Centers for Disease Control and Prevention (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students— United States, 2011–2012." *Morbidity and Mortality Weekly Report* 62(35): 729-730.

# Current e-cigarette use among students more than doubled between 2011 and 2012

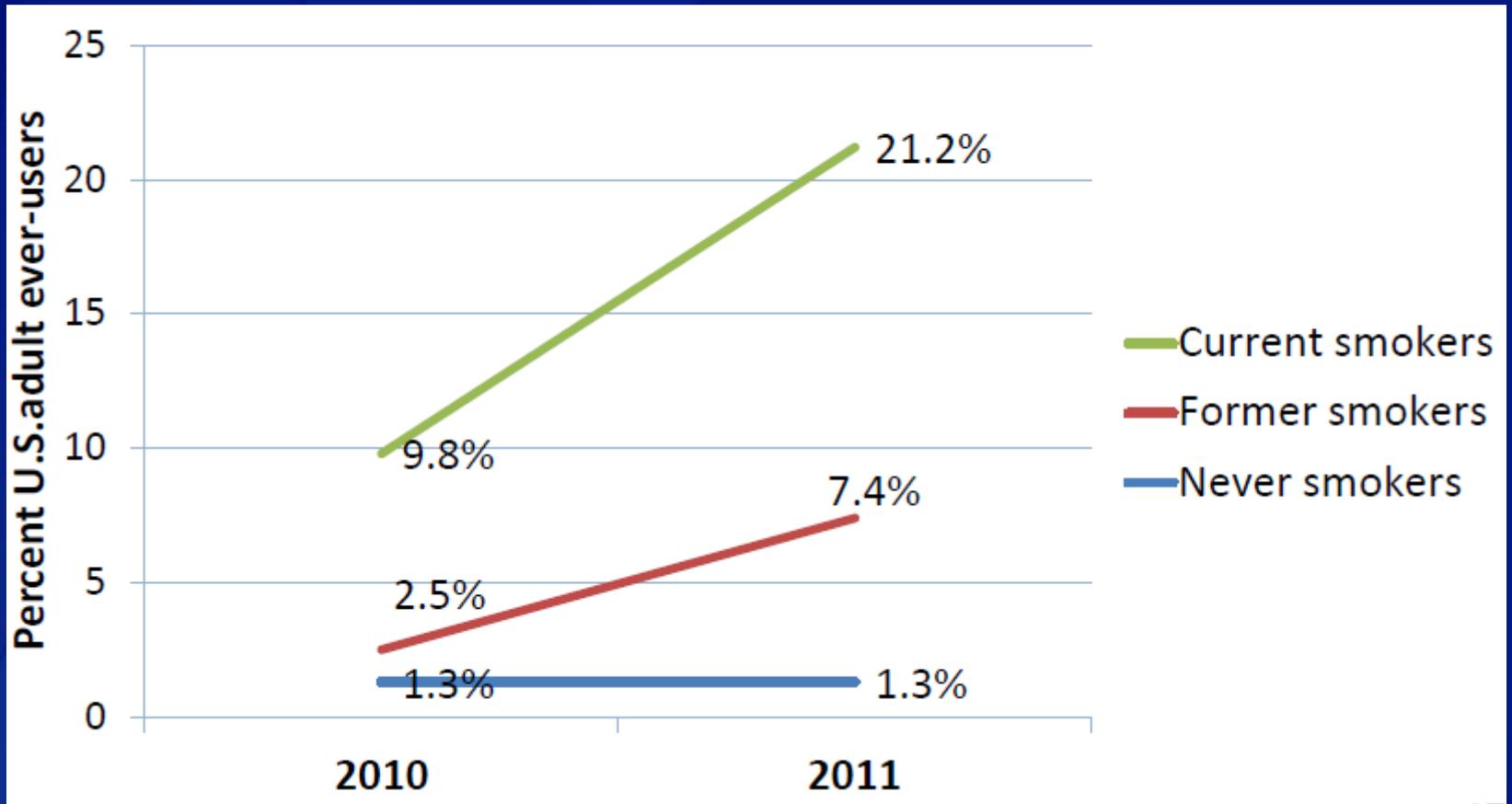
## *Current E-Cigarette Use\*, National Youth Tobacco Survey, United States*



\* Current use is defined as use on one or more days in the last 30 days

Centers for Disease Control and Prevention (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students— United States, 2011–2012." *Morbidity and Mortality Weekly Report* 62(35): 729-730.

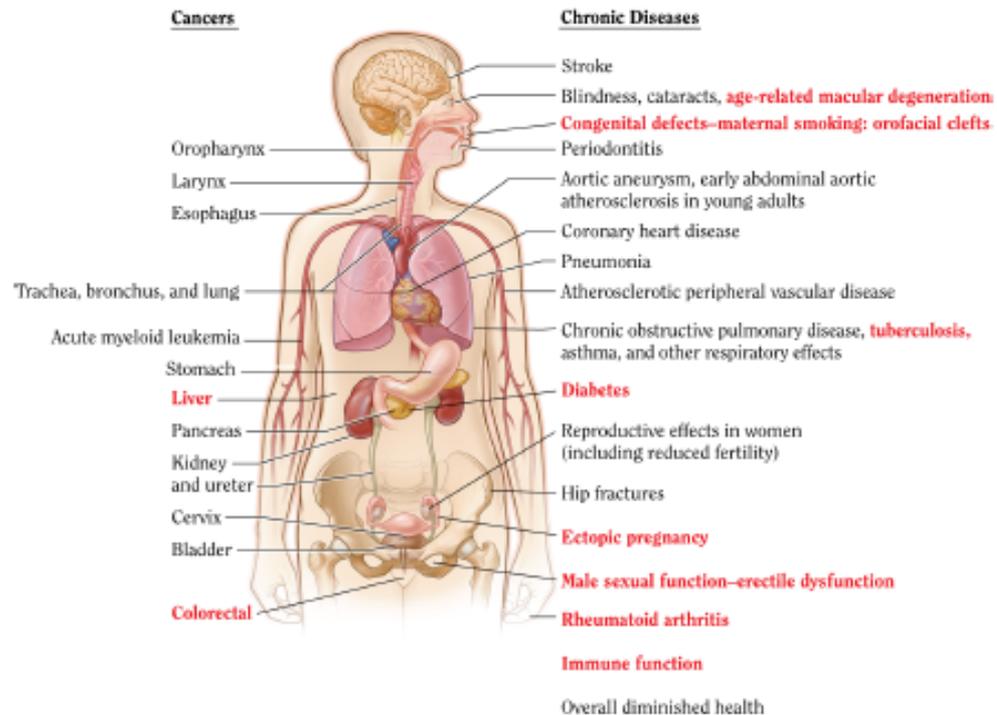
# E-Cigarette Ever Use 2010-2011



# Health Effects

Surgeon General's Report

Figure 1A The health consequences causally linked to smoking



Source: USDHHS 2004, 2006, 2012.

Note: The condition in red is a new disease that has been causally linked to smoking in this report.

# ENDS Potential for Harm

## ❑ Direct harm

- ❑ Expose children and adolescents, pregnant women, and non-smokers to 2<sup>nd</sup> hand aerosol, nicotine
- ❑ Poisonings among users or non-users
- ❑ Uncertain health effects of long term exposure
  - ❑ Pulmonary delivery of propylene glycol, glycerin, nicotine
  - ❑ Lower toxin burden than cigarettes, but not water vapor



# Nicotine

## 2014 Surgeon General's Report

1. At high enough doses, nicotine causes **acute toxicity**
2. Nicotine **activates** multiple biological pathways through which smoking increases risk for disease
3. Nicotine exposure during fetal development has lasting adverse consequences for **brain development**

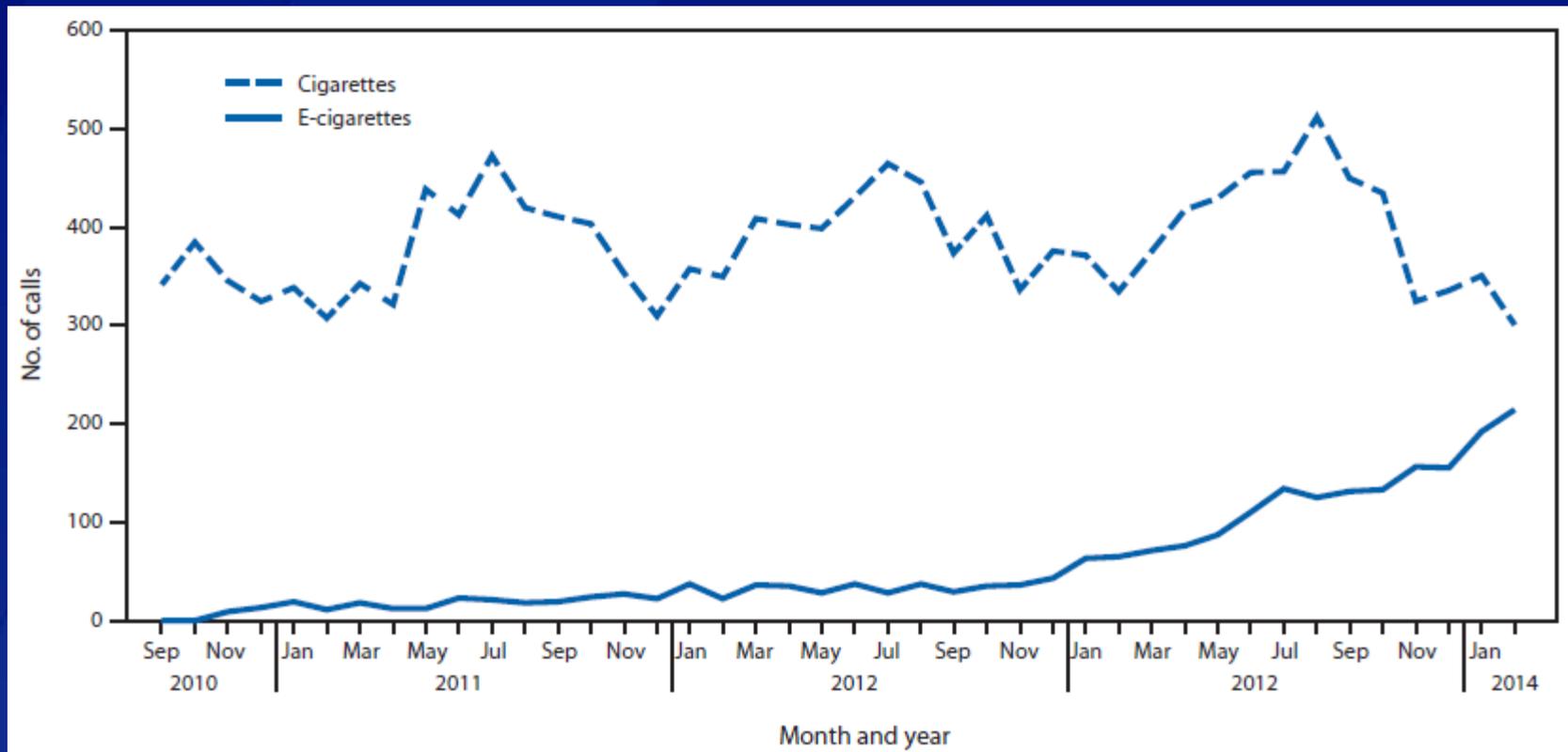


# Nicotine

## 2014 Surgeon General's Report

4. Nicotine adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes including **preterm delivery and stillbirth**
5. The evidence is suggestive that nicotine exposure during **adolescence** may have lasting adverse consequences for brain development
6. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to nicotine and risk for **cancer**.

# Number of calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014



# ENDS Aerosol Second Hand Exposure

- Use of e-cigarettes in the home or car could expose children/nonsmokers to nicotine, as well as to propylene glycol and/or glycerin, and other toxicants, through inhaled aerosolized vapor and surface deposits.
  - Studies of third hand tobacco smoke found that smoke components, including nicotine, are deposited and reemitted from indoor surfaces over time, and can result in substantial nicotine exposure levels.
  - Nicotine from e-cigarettes also deposits on indoor surfaces, creating a reservoir of nicotine that could be ingested, absorbed transdermally, or inhaled by children.

Singer BC, Hodgson AT, Nazaroff WW (2003) Gas-phase organics in environmental tobacco smoke: 2. Exposure-relevant emission factors and indirect exposures from habitual smoking. *Atmos Environ* 2003;37:5551–5561.  
Goniewicz ML, Lee L. Electronic cigarettes are a source of thirdhand exposure to nicotine. *Nicotine Tob Res* e-published August 30, 2014.

# ENDS Aerosol Second Hand Exposure

Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers<sup>☆</sup>



Montse Ballbè<sup>a,b,c,d,e</sup>, Jose M. Martínez-Sánchez<sup>a,c,f,\*</sup>, Xisca Sureda<sup>a,c,e</sup>, Marcela Fu<sup>a,c,e</sup>, Raúl Pérez-Ortuño<sup>g</sup>, José A. Pascual<sup>g,h</sup>, Esteve Saltó<sup>i,j</sup>, Esteve Fernández<sup>a,b,c,e</sup>

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## ABSTRACT

**Background:** There is scarce evidence about passive exposure to the vapour released or exhaled from electronic cigarettes (e-cigarettes) under real conditions. The aim of this study is to characterise passive exposure to nicotine from e-cigarettes' vapour and conventional cigarettes' smoke at home among non-smokers under real-use conditions.

**Methods:** We conducted an observational study with 54 non-smoker volunteers from different homes:

Montse Ballbè, Jose M. Martínez-Sánchez, Xisca Sureda, Marcela Fu, Raúl Pérez-Ortuño, José A. Pascual, Esteve Saltó, Esteve Fernández, Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers, *Environmental Research*, Volume 135, November 2014, Pages 76-80.

## Potential Harmful Interaction with Cigarettes

- ❑ Glamorize and renormalize tobacco use
- ❑ Lead to regular use of nicotine and/or use of cigarettes in youth or adult non-smokers
- ❑ Delay quitting and/or diminish the chances a smoker will quit by leading to long-term dual use
- ❑ Discourage smokers from using proven quit methods
- ❑ Increase former smoker relapse

# ENDS Potential for Benefit

Only under two circumstances:

- ❑ Are completely substituted for all combusted tobacco products in established adult smokers who would otherwise continue smoking
- ❑ Assist in rapid transition to a society with little or no use of burned products

# Dual Use

- ❑ Most e-cigarette users are current or former smokers
- ❑ Smokers often begin using e-cigarettes to cut back or quit smoking and become dual users
- ❑ Cutting back on traditional cigarettes does not reduce risk of all-cause mortality
- ❑ Cutting back on traditional cigarettes does not reduce risk of CVD in a linear fashion

U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2014.

U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking Attributable Disease. A Report of the Surgeon General. Atlanta Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2010.

Bjartveit and Tverday. Health Consequences of smoking 1-4 cigarettes per day. Tobacco Control 2005.

# Reducing smoking without quitting

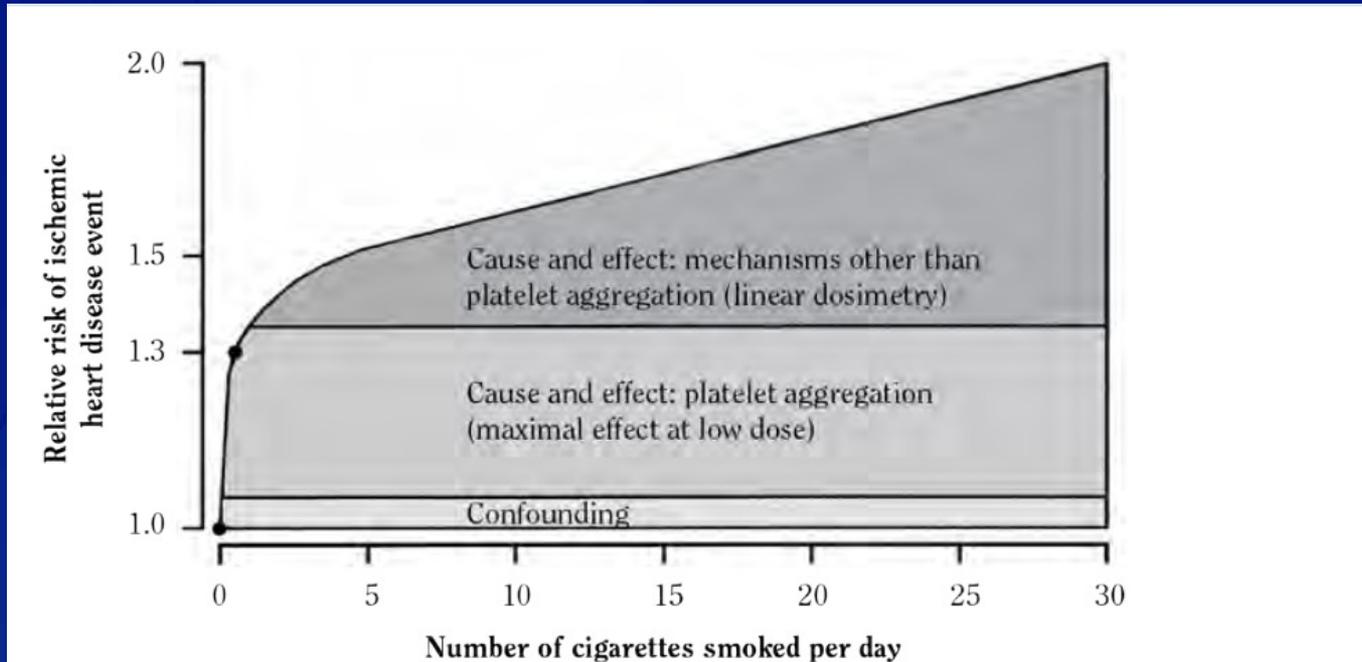


Figure 6.3 Dose-response relationship between number of cigarettes smoked per day and relative risk of ischemic heart disease

Source: [Law and Wald 2003](#). Reprinted with permission from Elsevier, © 2003.

Note: The dose-response relationship between exposure to tobacco smoke and ischemic heart disease events is compartmentalized into separate associations attributable to confounding (difference between smokers and nonsmokers in blood pressure, body weight, blood lipids, and diet), cause and effect maximal at low dose, and cause and effect with linear dosimetry.

U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking Attributable Disease. A Report of the Surgeon General. Atlanta Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2010.

# Provider knowledge and beliefs

- ❑ **Statewide sample of physicians and NPs providing care to children 11-17 years of age in MN, 2013**
  - Self-reported knowledge about e-cigarettes
    - 18% “nothing at all”
    - 65% “a little”
  - Very or somewhat uncomfortable talking to patients: 53%
- ❑ **National survey of obstetricians/gynecologists 2012**
  - 14% e- cigarettes have no adverse effects during pregnancy
  - 2/3 wanted to know more about the potential health effects of noncombustible tobacco products;
  - Only 5% believed themselves to be fully informed

Pepper, McRee, and Gilkey. Health providers' beliefs and attitudes about electronic cigarettes and preventive counseling for adolescent patients. *Journal of Adolescent Health* 2014.

England LJ, Anderson BL, Tong VT, et al. Screening practices and attitudes of obstetricians-gynecologists toward new and emerging tobacco products. *Am J Obstet Gynecol*. 2014 May 29

# Provider knowledge and beliefs

- Random sample of NC physicians surveyed in 2013
  - 48% reported that patients sometimes or frequently ask about e-cigarettes
  - 67% indicated that e-cigarettes are a helpful smoking cessation aid
  - 35% recommend e-cigarettes to their patients
  - 13% believed that e-cigarettes are approved by the FDA for smoking cessation

**What do existing  
recommendations say?**

# US Preventive Services Task Force

The screenshot shows the U.S. Preventive Services Task Force website. The header includes the logo, a search bar for 'Search USPSTF Topics', and options for 'E-mail Updates' and 'Text size'. The main navigation menu on the left lists: Home, Recommendations, Published Recommendations, Recommendations in Progress (highlighted), Information for Health Professionals, Information for Consumers, Public Comments and Nominations, Methods and Processes, About the USPSTF, Newsroom, and Announcements. The main content area is titled 'Recommendations in Progress' and includes a breadcrumb trail: 'You are here: Home >> Recommendations for Primary Care Practice >> Recommendations in Progress'. The text explains that topics are in review and development, and provides a diagram of the four stages of development. A yellow box titled 'Nominating a Topic' provides information on how to nominate a topic. The diagram shows four steps: Step 1: Develop a Research Plan (8 topics), Step 2: Systematically Review the Evidence (19 topics), Step 3: Develop a Draft Recommendation Statement (7 topics), and Step 4: Finalize the Recommendation Statement (1 topic). Below the diagram, the first step is detailed: 'Step 1: Research Plan Development' where an Evidence-based Practice Center (EPC) and the USPSTF create a research plan.

**U.S. Preventive Services TASK FORCE**

Search USPSTF Topics

E-mail Updates  Text size:

**Home** >> **Recommendations for Primary Care Practice** >> **Recommendations in Progress**

## Recommendations in Progress

The following topics are in review and development with the U.S. Preventive Services Task Force (Task Force). The purpose of a review is to update a recommendation based on new research or to add a new recommendation to the Task Force library.

Every recommendation involves several stages of development. The diagram below outlines the current stage for each topic now under review. The review process takes into account input from the medical and research community, stakeholders, and the general public.

The length of time for the entire recommendation process varies depending on the amount and type of available evidence and the time required for compilation of data into a draft recommendation, public comment periods and consideration of comments, and in-depth review and discussions among Task Force members.

### Nominating a Topic

The USPSTF makes recommendations about three types of clinical preventive services: screening tests, preventive medications, and counseling. Recommendations on preventive services are made for asymptomatic people (people without signs and symptoms of the conditions targeted by the preventive services). For more information and to nominate a topic, [click here](#).

### Stages of Development

Topics under review and development are listed below.

```
graph LR; S1[Step 1: Develop a Research Plan (8 topics)] --> S2[Step 2: Systematically Review the Evidence (19 topics)]; S2 --> S3[Step 3: Develop a Draft Recommendation Statement (7 topics)]; S3 --> S4[Step 4: Finalize the Recommendation Statement (1 topic)];
```

**Step 1: Research Plan Development**

Evidence-based Practice Center (EPC) and the USPSTF create a research plan that guides the recommendation process.

**Topics Currently in this Stage**

## III. Contextual Questions

Contextual questions will not be systematically reviewed and are not shown in the Analytic Framework.

1. What is the efficacy and safety of electronic cigarettes as an aid for smoking cessation in current adult smokers?

# North American Quitline Consortium

## NAQC Issue Paper

*NAQC's Issue Papers aim to provide critical knowledge on important quitline topics and guidance for decision making.*

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### **Integration of Tobacco Cessation Medications in State and Provincial Quitlines: A Review of the Evidence and the Practice with Recommendations (2014 Update)**

Tobacco dependence treatment professionals, including quitlines, are struggling with how to address e-cigarette use in the context of cessation. In the absence of established best practices, quitlines are creating treatment protocols for counseling and medications delivery. In the fall 2014, NAQC will publish an evidence synthesis on the topic to address these important questions.

[http://c.ymcdn.com/sites/www.naquitline.org/resource/resmgr/Issue\\_Papers/MedicationsUpdateIssuePaper.pdf](http://c.ymcdn.com/sites/www.naquitline.org/resource/resmgr/Issue_Papers/MedicationsUpdateIssuePaper.pdf)



# Regulation

## State action on ENDS

- ❑ No sales to minors (34 states)
- ❑ No use where smoking is not allowed (3 states)
- ❑ Additional promising strategies may include retailer licensing, marketing restrictions, taxation
- ❑ CDC will soon track ENDS legislation on [http://www.cdc.gov/tobacco/state\\_system/](http://www.cdc.gov/tobacco/state_system/)

## **States and Communities**

### **Rationale for prohibiting ENDS use in all places where smoking is not allowed**

- ❑ **Compare to clean air, not cigarette smoke**
- ❑ **There are no manufacturing standards**
- ❑ **Potential to expose youth, pregnant women, and non-smokers to aerosolized nicotine and other toxins**
- ❑ **No evidence public use is necessary for smokers to “switch” – could enable dual use**

# Smokeless Tobacco

# Smokeless Tobacco

- Types of smokeless tobacco:
  - Chewing tobacco (loose leaf, plug, or twist and may come in flavors)
  - Snuff (moist, dry, or in packets [U.S. **snus**])
  - Dissolvables** (lozenges, sticks, strips, orbs)



# Snus

- ❑ A type of moist snuff
- ❑ Packaged in ready-to-use pouches that resemble small tea bags
- ❑ Pouch is placed between cheek or teeth and gums, does not require spitting
- ❑ Market share data unavailable





# Dissolvables



Form	Description	Market Share (in 2011)
Lozenges	Resemble pellets or tablets	Data unavailable
Orbs	Resemble small mints	Data unavailable
Sticks	Toothpick-like appearance	Data unavailable
Strips	Thin sheets like breath or medication strips	Data unavailable

## Health Effects (Smokeless)

- ❑ Nicotine addiction
- ❑ Cancer of the mouth, esophagus and pancreas
- ❑ Leukoplakia, gum disease
- ❑ Increased risk for preterm birth and stillbirth when used during pregnancy (Swedish snus)
- ❑ Nicotine poisoning in children
- ❑ May increase the risk of death from heart disease and stroke

U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2014.

Piano MR, Benowitz NL, FitzGerald GA, et al. Impact of smokeless tobacco products on cardiovascular disease: Implications for Policy, Prevention, and Treatment. A policy statement from the American Heart Association. *Circulation* 2010;122:1520-44.

# US Snus

**Table 3**  
Mean values of total moisture, total nicotine, and pH and unprotonated nicotine using either 10 mL or 20 mL of water for each domestic oral tobacco product type.

Tobacco type	Number of brands	Total moisture (%) Mean	Total nicotine (mg/g, wet) Mean	pH		Unprotonated nicotine (mg/g, wet)	
				Mean		Mean	
				10 mL	20 mL	10 mL	20 mL
Dry snuff	5	6.52	17.6	5.86	5.99	0.13	0.18
Loose leaf	3	21.9	6.29	5.74	5.82	0.04	0.04
Twist	3	15.0	30.6	5.34	5.39	0.10	0.11
Plug	4	18.3	8.68	5.48	5.55	0.03	0.03
Dry snuff (pouch)	4	6.18	11.7	6.94	6.98	1.08	1.14
Snus	3	25.9	10.1	7.64	7.64	2.97	3.01

Lawler, Stanfill, Zhang, Ashley, Watson. Chemical characterization of domestic oral products: Total nicotine, pH, unprotonated nicotine, and tobacco-specific N-nitrosamines. Food and Chemical Toxicity 2013 57:380-6.

# US Snus

**Table 5**

Levels of five tobacco-specific N-nitrosamines found in 29 brands representative of seven types of oral tobacco marketed in the United States.

Tobacco product type	Brand	NAB <sup>a</sup> (ng/g, wet)		NAT (ng/g, wet)		NNK (ng/g, wet)		NNN (ng/g, wet)		NNAL (ng/g, wet)		Total TSNA <sub>s</sub> (ng/g, wet)
		Mean <sup>b</sup>	(SD) <sup>c</sup>	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Sum
Plug	Days o Work	30	(10)	762	(79)	340	(28)	2920	(900)	41	(1.1)	4090
	Conwood Sun Cured	69	(10)	1520	(260)	844	(226)	3130	(260)	11	(11)	5580
	Levi Garrett	199	(29)	1330	(100)	941	(78)	5140	(90)	140	(49)	7750
	Taylor's Pride Plug Chew	183	(6.1)	1400	(100)	803	(83)	4640	(350)	188	(44)	7210
Loose Leaf	Beech-Nut Chew	23	(2.3)	563	(28)	300	(32)	1640	(60)	21	(0.9)	2550
	Taylor's Pride Chew	76	(17)	796	(72)	306	(22)	2830	(240)	90	(80)	4100
	Red Man Chew	16	(2.5)	351	(27)	238	(23)	942	(22)	20 <sup>d</sup>	(23)	1550
Snus	Camel Snus Frost	28	(1.3)	265	(37)	146	(13)	425	(53)	20	(3.0)	884
	Camel Snus Spice	28	(8.5)	259	(35)	84	(22)	369	(59)	21	(12)	761
	Camel Snus Original	26	(10)	251	(32)	140	(58)	389	(111)	20	(14)	826
Dissolvable	Stonewall Wintergreen	10	(0.2)	218	(9.3)	49	(5.4)	94	(5.8)	n.d.	(-)	271
	Stonewall Java	11	(1.3)	251	(8.0)	63	(3.5)	103	(17)	n.d.	(-)	428
	Stonewall Natural	11	(1.5)	247	(4.0)	73	(6.4)	117	(8.5)	n.d.	(-)	448
	Ariva Java	7.0	(1.4)	178	(11)	54	(5.2)	74	(6.8)	n.d.	(-)	313
	Ariva Wintergreen	8.0	(0.8)	176	(3.8)	52	(1.4)	77	(14)	n.d.	(-)	313
	Camel Orbs Mellow	15	(0.4)	176	(15)	147	(7.1)	189	(3.7)	5.6	(1.4)	533
	Camel Orbs Fresh	17	(0.4)	194	(26)	202	(4.4)	193	(8.7)	5.8	(1.8)	612

Lawler, Stanfill, Zhang, Ashley, Watson. Chemical characterization of domestic oral products: Total nicotine, pH, unprotonated nicotine, and tobacco-specific N-nitrosamines. Food and Chemical Toxicity 2013 57:380-6.

## US Snus

- ❑ Camel and Marlboro Snus are top-selling brands
- ❑ 2006-2010, 147 samples
- ❑ Compared with 2006
  - Pouch size increased in both brands
  - Camel snus pouches were higher in total, unprotonated nicotine and NNN /NNK by 1.9, 2.4, 3.3- fold respectively.
  - Marlboro snus pouches were higher in total, unprotonated nicotine by 2.1, 1.9, fold, respectively but 1.5-fold lower in NNN /NNK.

- Stepanov I, Jensen J, Biener L, Bliss RL, Hecht SS, Hatsukami DK. Increased pouch sizes and resulting changes in the amounts of nicotine and tobacco-specific N-nitrosamines in single pouches of Camel Snus and Marlboro Snus. *Nicotine Tob Res.* 2012 Oct;14(10):1241-5.

## US Snus

- **2011, 216 samples gathered from 6 US regions, compared with samples collected in 2010**
  - TSNA levels increased in Marlboro and Camel snus, and in some Camel dissolvables
  - Unprotonated nicotine levels did not change compared with 2010, but varied by region, as much as 3.2-fold

Stepanov I, Biener L, Yershova K, Nyman AL, Bliss R, Parascandola M, Hatsukami DK. Monitoring tobacco-specific N-nitrosamines and nicotine in novel smokeless tobacco products: findings from round II of the new product watch. *Nicotine Tob Res.* 2014 Aug;16(8):1070-8.

## TobaccoToday

[home](#) [archives](#) [about](#)

[← The C-Store Pipe-Tobacco Opportunity](#)

[It's Official: Big Pharma is Lobbying Against Electronic Cigarettes- Dr. Michael Siegel →](#)

### **Swedish Match submits 100,000+ page Modified Risk Tobacco Product (MRTP) application to FDA to truthfully market General Snus to smokers as less hazardous alternative to cigarettes**

June 14th, 2014 | [Current Issues, Regulations: FDA etc.](#), [Snus, Snuff & Alternative Products in US Markets](#), [tobacco](#), [Tobacco Harm Reduction](#) | [ECigInsider](#)

**RICHMOND, Va. — Copyright 2014 The Associated Press**- Smokeless tobacco maker Swedish Match is asking the Food and Drug Administration to certify its General-branded pouches of tobacco as less harmful than cigarettes.

The company with its North American headquarters in Richmond, Virginia, is filing an application with the FDA to approve the snus (pronounced "snoose") products as "modified risk."

<http://www.tobaccotoday.info/2014/06/14/swedish-match-submits-100000-page-modified-risk-tobacco-product-mrtp-application-to-fda-to-truthfully-market-general-snus-to-smokers-as-less-hazardous-alternative-to-cigarettes/>

# Dissolvables

WINSTON-SALEM JOURNAL  
Tuesday, October 28th, 2014

JOURNAL PREPZONE  
A fresh look on high school sports  
Sponsored by FLO

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## R.J. Reynolds scales back marketing of dissolvable tobacco products

Story Comments Image (1) Print Font Size: - +

Tweet 0 0 0

Posted: Wednesday, July 31, 2013 11:05 am | Updated: 11:56 am, Fri Aug 2, 2013.  
Richard Craver/Winston-Salem Journal



Courtesy of R.J. Reynolds

R.J. Reynolds Tobacco Co. has struggled to the extent that it is limiting future marketing of the products: a pellet (Camel Orbs), a twisted stick the size of a toothpick (Camel Sticks) and a film strip for the tongue (Camel Strips).

After spending more than 4 1/2 years in five test markets, including Charlotte, R.J. Reynolds Tobacco Co. has struggled to gain consumer traction for its trio of dissolvable tobacco products.

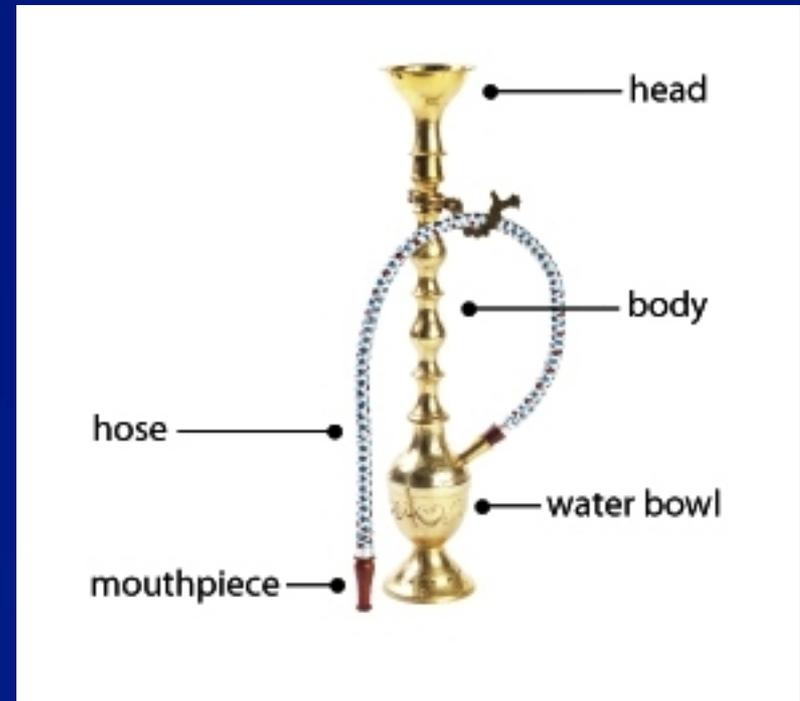
It has struggled to the extent that it is limiting future marketing of the products: a pellet (Camel Orbs), a twisted stick the size of a toothpick (Camel Sticks) and a film strip for the tongue (Camel Strips).

The goal has been making its tobacco products more accessible within a society that's clamping down on smoking. Reynolds

[http://www.journalnow.com/business/business\\_news/local/article\\_9d001b58-f9f2-11e2-8fad-0019bb30f31a.html](http://www.journalnow.com/business/business_news/local/article_9d001b58-f9f2-11e2-8fad-0019bb30f31a.html)

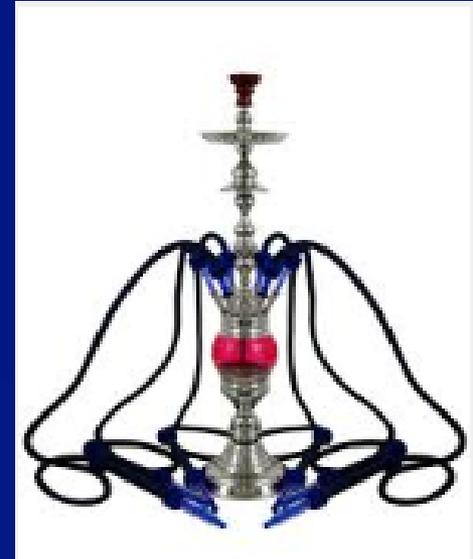
# Hookah

- ❑ Water pipes that are used to smoke specially made tobacco that comes in different flavors, such as apple, mint, cherry, chocolate, coconut, licorice, cappuccino
- ❑ Also called *narghile*, *argileh*, *shisha*, *hubble-bubble*, and *goza*
- ❑ Often smoked in groups, mouth piece shared.



# Hookah

- ❑ Many users think it is less harmful, hookah smoking has many of the same health risks as cigarette smoking (cancer, cardiovascular disease)
- ❑ Hookahs produce high levels of carcinogens and carbon monoxide
- ❑ An hour-long hookah session can involve 200 puffs, and 90,000 ml of smoke inhaled, compared with 20 puffs from smoking a single cigarette, or 500 ml smoke



# Hookah

- ❑ **High school seniors**
  - 1 of 5 boys, 1 of 6 girls used hookah in the last year
- ❑ **College students**
  - 22-40% used in last year
- ❑ **Adults**
  - 18.2% of 18-24 year olds use everyday, some days, or rarely



# College Students

- ❑ Study of 2 universities in the Southeast, 2000 students
- ❑ Marijuana (19.2%) and hookah (16.4%) were the most commonly used products in the last month
- ❑ E-cigarettes were lower (4.5%)
- ❑ There were high rates of concurrent use, esp. in e-cigarette users
- ❑ Marijuana was the most positively perceived product followed by hookah and e-cigarettes

# Hookah

## PERCEPTIONS OF TOBACCO PRODUCTS AND MARIJUANA

5

TABLE 2. Concurrent use of tobacco products and marijuana

Product	Cigarettes <i>n</i> = 315 16.0%	Cigar products <i>n</i> = 293 14.9%	Smokeless tobacco <i>n</i> = 51 2.6%	Hookah <i>n</i> = 322 16.4%	Electronic cigarettes <i>n</i> = 88 4.5%	Marijuana <i>n</i> = 377 19.2%
Cigarettes	–	43.3%	56.9%	41.0%	71.6%	38.7%
Cigar products	40.3%	–	54.9%	39.8%	46.6%	47.5%
Smokeless tobacco	9.2%	9.6%	–	7.1%	17.0%	5.0%
Hookah	41.9%	43.7%	45.1%	–	54.5%	41.1%
Electronic cigarettes	20.0%	14.0%	29.4%	14.9%	–	12.5%
Marijuana	46.3%	61.1%	37.3%	48.1%	53.4%	–

*Note:* All chi-squared *p*-values < 0.001. To interpret, among users of column heading, % also using row heading in the past 30 days. Example: Of the 315 cigarette smokers, 40.3% also smoked cigar products in the past 30 days.

# FDA Center for Tobacco Products

Proposed newly “deemed” products would include electronic cigarettes, cigars, pipe tobacco, **certain dissolvables** that are not “smokeless tobacco,” gels, and **waterpipe tobacco**. Once the proposed rule becomes final, FDA can use regulatory tools, such as age restrictions and requiring scientific review of new tobacco products and claims to reduce tobacco-related disease and death

## FDA Regulation of e-Cigarettes

Only e-cigarettes that are marketed for therapeutic purposes are currently regulated by the FDA Center for Drug Evaluation and Research (CDER). Currently, the FDA Center for Tobacco Products (CTP) regulates

- cigarettes,
- cigarette tobacco,
- roll-your-own tobacco, and
- smokeless tobacco.

FDA has issued a proposed rule that would extend the agency’s tobacco authority to cover additional products that meet the legal definition of a tobacco product, such as e-cigarettes. FDA’s [Extending Authorities to Additional Tobacco Products webpage](#) offers more information on the proposed rule.

**For more information on current regulation:**

- [Tobacco Product Regulation](#)
- [Nicotine-Containing Products](#)

# Key Take Away Points



## *Summary*

- ✓ ENDS are not “safe”
- ✓ Unregulated sale and distribution driving demand
- ✓ Cessation claims are unproven
- ✓ Potential for harm and benefit depends on the context of combusted tobacco products
- ✓ Dual use/delayed quitting is a major concern

# Key Take Away Points



- ✓ Emerging smokeless products are not without risk and their use can result in exposure to high levels of nicotine and carcinogens
- ✓ Some companies might be able to make reduced harm claims if applications are accepted by the FDA.
- ✓ Hookah is used less frequently than cigarettes, but a single hookah session can result in high levels of exposure to carcinogens and carbon monoxide
- ✓ Many young adults who use hookah use other tobacco products concurrently

# Contact

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CDC Office on Smoking and Health



[www.cdc.gov/tobacco](http://www.cdc.gov/tobacco)



# Resources

## USPHSTF

- <http://www.uspreventiveservicestaskforce.org/>
- <http://www.fda.gov/TobaccoProducts/default.htm>
- [http://www.tobaccofreekids.org/tobacco\\_unfiltered/tag/e-cigarettes](http://www.tobaccofreekids.org/tobacco_unfiltered/tag/e-cigarettes)



## CDC

- <http://www.cdc.gov/tobacco/campaign/tips/>
- <http://www.cdc.gov/reproductivehealth/TobaccoUsePregnancy/Providers.html>



## Online training

- <http://iml.dartmouth.edu/education/dsr/>
- <https://www.smokingcessationandpregnancy.org/>



# Resources

## Electronic cigarettes

- <http://www.fda.gov/TobaccoProducts/default.htm>
- [http://www.tobaccofreekids.org/tobacco\\_unfiltered/tag/e-cigarettes](http://www.tobaccofreekids.org/tobacco_unfiltered/tag/e-cigarettes)
- <http://www.cdc.gov/reproductivehealth/TobaccoUsePregnancy/Providers.html>
- <http://publichealthlawcenter.org/programs/tobacco-control-legal-consortium>



## Other statements/recommendations